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MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
09/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,560	HAREL ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55,79-85,87 and 101-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-55,79-85,87 and 101-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20100916, 20100418, 20100428, 20100505, 20100525, 20100603, 20100628, 20100701, 20100705, 20100713, 20100719, 20100803, 20100818, 20100825, 20100826, 20100907.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. PCT/IL03/00736, US 10/237,263, PCT/IL00/00566, US 09/914,889, PCT/IL00/00132, and US 60/123,532, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The Examiner was unable to find support for the combination of an electrode mounted attached to muscle tissue and electrifying that electrode in a manner suitable for blood glucose level control, wherein the manner includes a pulse train having the claimed ranges of signal parameters, as required by all pending claims. For instance, Applicant appears to rely on the embodiment drawn to a mesh electrode on the pancreas and a needle ground electrode inserted into the abdominal muscle wall (*e.g.*, page 26) to

support the electrode limitations. However, the examiner was unable to locate, in any of the priority documents, disclosure that this electrode configuration is used with the signal parameters disclosed for stomach or intestine stimulation (but only pancreatic stimulation). This appears to be a mixing of embodiments. Furthermore, the examiner was unable to find support for the claimed ranges of pulse width and pulse train duration. Disclosure of species within the claimed ranges does not provide written description support for the claimed ranges. If applicant asserts that such written description support is present in the priority documents, the examiner respectfully requests citation by document and page number.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 52-55, 79-85, 87, and 101-127 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner was unable to find support in the originally-filed disclosure for the combination of claim elements including the following:

4. In regards to claim 52, the support for the electrode limitations asserted by applicant are drawn to the embodiment of a mesh electrode on the pancreas and a

needle ground electrode inserted into the abdominal muscle wall (*e.g.*, page 26). However, the examiner was unable to locate disclosure that this electrode configuration is used with the signal parameters disclosed for stomach or intestine stimulation (which is apparently included within the scope of the claims per, e.g., claim 110). This appears to be an unsupported mixing of embodiments. Furthermore, the examiner was unable to find support for the claimed ranges of pulse width and pulse train duration. For example, page 45 discloses that the pulse width can be 1ms to 1s, but does not support the currently claimed range of "1 ms to 2 seconds long." Additionally, the examiner was unable to find support for determining a synchronization between electrification of the electrode and an action potential "by one or both of" sensing electrical activity in tissue via the electrode and causing the action potential by sending a pacing signal through the electrode. Lastly, the examiner was unable to find support for circuitry configured to create the temporal relationship of the "determining a synchronization of" and electrifying the electrode wherein said electrification is not said pacing signal and is not excitatory to muscle tissue.

5. In regards to claim 53, the examiner was unable to find written description support for circuitry using a closed-loop system with a stored desired blood glucose level and stimulates using one of several stored sets of stimulation parameters that is selected to be more than sufficient to reduce glucose levels. Page 43 of the disclosure recites, "this reduction in side effects is used to design control schemes which err on the side of over stimulation." The particulars of claim 53 appear to be a specific implementation of which "possession" has not been shown. In other words, this

appears to be one such control scheme which the disclosure indicates *could be* designed, but the disclosure does not indicate *possession of this actual design* as of the time of filing.

6. In regards to claim 79, "without mediation of insulin" appears to lack support. Although mediation of glucagon would appear to be a "non-insulin" manner, the disclosure appears to lack possession of an embodiment wherein preclusion of both glucagon ("non-insulin") and insulin are mediated.

7. In regards to claims 106, 107, 110, 111, 113-118, 120, and 121, the limitations appear to be drawn to the embodiment wherein the electrode is attached to the stomach or intestine. However, applicant appears to rely on the "needle ground electrode in the abdominal wall" embodiment for support of claim 52. This appears to be an unsupported mixing of embodiments.

8. In regards to claim 115, the examiner was unable to find support for the claimed range of electrifying an electrode for "at least 15 minutes during digestion of a meal"

9. In regards to claim 116, the examiner was unable to find support for the claimed range of "at least 0.5 seconds" or "for at least 5 such detections."

10. In regards to claim 117, the examiner was unable to find support for the claimed range of "at least 20 seconds."

11. In regards to claim 118, the examiner was unable to find support for the claimed range of "less than 10 seconds."

12. In regards to claim 119, the examiner was unable to find support for stimulation that "does not affect nervous tissue." Any negative limitation or exclusionary proviso

must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

13. In regards to claim 120, the examiner was unable to find support for electrification of the electrode "also in a manner which paces said stomach."

14. In regards to claim 121, the examiner was unable to find support for stimulation that "does not cause propagation of an action potential in said stomach or a pancreas." Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

15. In regards to claims 126 and 127, the examiner was unable to find written description support for the ranges of a pulse train of 1-10 seconds or a series of 1 second pulses in response to detection of an action potential in the stomach for at least 5 such detections.

16. Claims 52-55, 79-85, 87, and 101-127 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining a synchronization of electrification of an electrode by sensing electrical activity in tissue

via the electrode, does not reasonably provide enablement for synchronization of electrification of an electrode relative to a time of an action potential *by causing said action potential*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Firstly, it appears to be a logical impossibility to determine synchronization (*i.e.*, happening at the same time) of electrode activation and an action potential by causing *said* action potential because causing the action potential requires a synchronous electrode activation. In other words, it appears that the claim recites circuitry that determines a time to activate an electrode in synchrony with an action potential by creating the very action potential that the electrode is intended to synchronize with.

17. Furthermore, it would seem that some sort of sensing by the electrode is required to "determine a synchronization" because there is no other means set forth in the claim to acquire information of any kind. Claim 52 includes an embodiment wherein synchronization of electrification is determined only by "causing said action potential" (see the "one or both of" language of line 5). Some sort of means for sensing or acquisition of information is required to make "a determination."

18. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

19. The claim recites closing a loop to a stored "desired" blood glucose level using electrical stimulation, and selecting a set of stimulation parameters selected to be more than sufficient to reduce blood glucose levels to said desired, safe, glucose level. Based on the sparse guidance provided by the prior art and Applicant at, *e.g.*, page 22 of "over stimulat[ing] in cases of doubt," the lacking description of examples using this algorithm, and the breadth of the claim, the examiner respectfully asserts that practicing this invention would require undue experimentation. See MPEP § 2164.01(a). If the system is stimulating more than necessary for the desired modification, does this not just mean that the increased modification is the "desired" level, and the lower level is merely arbitrary? Since this system implements a pre-programmed algorithm, isn't the "more than sufficient" value just the desired value? For example, if the medical literature indicates that 100 mg/dl of glucose is normal/desired, would merely setting the threshold to 120 mg/dl if the device is not "certain" be sufficient to meet the limitations of the claim? In that case, is the 120 mg/dl level now just the "desired" level?

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 52, 53, 104, 107, 111, 117, 118, 122, and 123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. In regards to claim 52, it is unclear whether the "electrification" of line 12 refers to the "electrification" of line 4 or line 9.

23. In regards to claim 53, "said desired, safe, glucose level" lacks antecedent basis.

24. In regards to claims 53-55, 79-82, 85, 101-105,107-109, 112, and 115-123, it is unclear to which circuitry "said circuitry" refers ("circuitry" or "timing circuitry") and it is unclear to which "electrification" the claims refer (line 4, 9, or 12 of claim 52).

25. In regards to claims 117, 118, and 127, nothing has been set forth to detect action potentials in the stomach, rendering the claim incomplete. The examiner is considering the timing circuitry to perform this function (as in claim 116), but the claim should be amended to clarify.

Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

27. Claims 52, 54, 55, 79-85, 87, 101-124, and 126 are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al. (US 5,231,988, hereinafter "Wernicke").

28. In regards to claims 52, 87, 106, 110, and 111, Wernicke discloses an apparatus for blood glucose control (abstract) comprising an implantable electrode capable of being mounted attached to muscle tissue in the abdominal cavity (col. 5, line 68 to col.

6, line 3 and col. 7, lines 13-29); timing circuitry which determines a synchronization of electrification of said electrode to a time of an action potential in tissue by causing said action potential by sending a pacing signal through said electrode (col. 8, lines 3-16 -- determined by the patient input device and activation is synchronous with "an action potential in tissue" because the stimulation causes action potentials in at least the vagus nerve); and circuitry which electrifies said at least one electrode in a manner suitable for blood glucose level control, said manner including at least one pulse train wherein each pulse is between 1ms and 2s long, wherein said electrification is not said pacing signal and is not excitatory to muscle tissue (Fig. 4 and Table II -- the "causing said action potential stimulation is the first of the train of pulses, and the "suitable for blood glucose level control" pulses are the subsequent pulses in the train). Wernicke's disclosure that the electrode is implanted "at or near the stomach" is an implicit disclosure that the electrode is "mounted attached to muscle tissue," at least indirectly, by virtue of the innervation of the vagus into the muscle tissue at the stomach, and the electrode 10 (conductive housing). Additionally and alternatively, Wernicke's electrode is necessarily capable of being mounted attached to stomach, duodenum muscle tissue, or any other nearby anatomical structure by, *e.g.*, suturing the electrode in place on muscle tissue in the abdominal cavity, as disclosed by Applicant on pages 56 and 57 of the specification.

29. In regards to claim 54, the circuitry is semi-open loop where a relatively long stimulation series is applied without feedback to return glucose to a normal level (col. 9, lines 41-50).

30. In regards to claim 55, the system is an open loop system (col. 9, lines 51-55).

31. In regards to claim 82, the apparatus is programmed with information pertaining to slow-acting chemical-based insulin therapy provided to a pancreas (col. 8, lines 3-16 - knowledge that insulin is needed after meals and that the electrical therapy causes release of insulin).

32. In regards to claims 83-84, the apparatus further comprises an automatic glucose sensor to detect a need for an acute insulin response (col. 7, lines 35-40).

33. In regards to claims 103, 104, and 109, the circuitry electrifies the electrode at 5 Hz with a pulse width of less than 30ms (Tables I and II).

34. In regards to claim 107, the electrode is electrified in synchrony with the electrical activity determined by the timing circuit (because the electrode causes the electrical activity determined by the timing circuit). Further, this activity "corresponds" to the propagation of action potentials because the activity is caused by action potentials, whether intrinsic or invoked by therapy. Nothing has been set forth to actually sense action potentials -- the "sensing" of claim 52 is recited in the alternative.

35. In regards to claim 108, the apparatus reduces high blood glucose levels, but does not reduce normal blood glucose levels (col. 7, lines 30-68).

36. In regards to claims 79-81, 85, 101, 102, 105, 108, 109, 112, 119, 120, and 121, Wernicke discloses circuitry that electrifies electrodes with a frequency, pulse width, amplitude, and other signal parameters (Table I) disclosed by Applicant at pages 44-48 to be effective in producing the claimed results. As such, Wernicke's circuitry necessarily produces the claimed field, regardless of whether these properties were recognized at the time.

37. In regards to claims 113 and 114, the electrode is a bipolar electrode mounted to a lead (col. 10, lines 33-35) and is a size capable of being sutured to a muscle.

38. In regards to claims 115 and 122, the circuitry includes an input to indicate digestion (col. 8, lines 3-16) and electrifies the electrode for at least 15 minutes in response during digestion (Tables I and II).

39. In regards to claim 123, the electrode is electrified with a frequency of 50-150 Hz (Tables I and II).

40. In regards to claim 124, the timing circuitry comprises pacing circuitry (Tables I and II).

41. In regards to claim 126, the train is between 1 and 10 seconds long (Table II).

42. In regards to claims 116-118, the "sensing electrical activity" limitation of claim 52 is recited in the alternative, and the rejection relies on the "causing said action potential" limitation.

Claim Rejections - 35 USC § 103

43. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

44. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

45. Claims 125 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke. Wernicke discloses the essential features of the claimed invention including a sensor to detect the beginning of digestion (see above) and circuitry that applies the claimed signal parameters (see above) and thus produce the claimed effects (see above), but does not disclose a sensor that detects action potentials in the stomach. However, it is well known in the art to provide gastric stimulators with a sensor that detects action potentials in the stomach to provide the predictable result of providing therapy only when needed, as indicated by digestion activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wernicke by providing the gastric stimulator with a sensor that detects action potentials in the stomach to provide the predictable result of providing therapy only when needed, as indicated by digestion activity.

Allowable Subject Matter

46. Claims 53 does not have art rejections applied, but remains rejected under 112(1) and (2).

Response to Arguments

47. Applicant's arguments with respect to claims 52-55, 79-85, 87, and 101-127 have been considered but are not persuasive in part, persuasive in part, and moot in view of the new ground(s) of rejection in part.

48. In regards to the priority claims, it is well settled that a claim for priority requires enablement and written description support for the invention in the priority document. The invention is what is now claimed, and the priority document must fully support the claim in the instant application by showing that Applicant "possessed" what is now claimed. See MPEP § 201.11(I)(B). The examiner was unable to find such support in the priority document cited by Applicant (US 7,006,871) or any of the other documents cited for support. For instance, the priority document lacks discussion of timing circuitry which determines a synchronization of electrification of said electrode; or circuitry which electrifies at least one electrode with a pulse width in the range of 1ms to 2s wherein the electrification is not said pacing signal and is not excitatory to muscle tissue.

49. Furthermore, Applicant relies upon column 25, line 5 for support of "at least one implantable electrode configured to be mounted attached to muscle tissue in the abdominal cavity," and the examiner is required to interpret claims under their broadest reasonable interpretation in light of the specification. Because Applicant maintains that at least claim 52 is fully supported by the priority document, the examiner must interpret the claim in light of this disclosure. This disclosure of "muscle tissue" apparently pertains to using an electrode as a ground on the abdominal wall, and this priority document does not refer to mounting the electrode to the stomach, intestines, or even

refer to the stomach or intestines as "muscle" (as common usage of the term "muscle" does not usually include the stomach or intestines). However, it appears that Applicant is attempting to "bootstrap" disclosures of stimulation in these locations from the instant application to the use of "abdominal wall" (as a muscle) in the priority document. In other words, this appears to be an attempt to both retain the earlier priority date and incorporate the various embodiments from the instant application to broaden the meaning of "muscle". Based on Applicant's insistence that the priority document fully supports claim 52, the examiner is interpreting "muscle tissue in the abdominal cavity" consistent with the disclosure of muscle tissue in the abdominal cavity in the priority document (*i.e.*, with no mention of the organs of the GI tract being considered "muscles").

50. Applicant's arguments with respect to the priority claim and 112(1) support in the instant application are based generally on the idea that the instant claims do not contradict or are not repugnant to the disclosure in the priority document or the instant disclosure (e.g., page 9, "[i]t is clear from the structure of the application and from the explicit language in each of these sections and from the explicit language at the top of Col. 26, that it is intended that the scope of the claims include such combinations as the applicants have made"). However, broad language with sweeping scope does not necessarily show possession of each combination or embodiment, however later conceived, that falls within this scope. For instance, disclosure of a voltage range of 1-10V does not provide written description support for a claim drawn to 5V, nor does it support a claim drawn to 5-1,000V, even though there is overlap of scope. Likewise

disclosure of stimulating a pancreas with a mesh electrode and a ground needle electrode inserted in the abdominal wall to stimulate the pancreas coupled with disclosure that "combinations of the above features are also considered to be within the scope of some preferred embodiments" (see Col. 26 of the priority document) does not provide support for attaching an electrode to the stomach to stimulate the stomach (as currently claimed) simply because this embodiment is not precluded by the disclosure. Similarly, broad ranges of signal parameters are given, but where is the disclosure of the range of pulses of 1ms to 2s in the priority document (or instant application), or the temporal relationship or control algorithm of the second two paragraphs of claim 52? See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species).

51. In regards to the written description rejections:

a. Claim 79: the rejection is based on the idea that applicant has disclosed control in a non-insulin manner (e.g., by controlling glucagon), but does not disclose that insulin is not also controlled. The claim recites that insulin is not controlled.

b. Claims 106, 107, 110, 111, 113-118, 120, and 121: the examiner maintains that this is a mixing of embodiments. As used in claim 52, "attached to muscle tissue" refers to the abdominal wall, but these claims refer to the stomach.

c. Claim 115: Applicant's citation failed to show possession of stimulating for at least 15 minutes during digestion of a meal.

d. Claim 116: although the cited ranges or values may overlap or include the now claimed ranges, this is not written description support because it does not show possession of the ranges actually claimed.

e. Claims 117 and 118: "less than 20 seconds" is not the same range as "20 seconds or less".

f. Claim 119: the cited passage makes no mention of nervous tissue.

g. Claim 120: the noted details are not disclosed as being in combination with the other claim elements.

h. Claim 121: the cited passage makes no mention of action potentials.

52. In regards to the enablement rejection of claim 53, Applicant that the rejection is moot. However, the examiner maintains the rejection for the reasons set forth above. For instance, if the present invention is programmed for overshooting a desired value, is the "overshot" value now just the desired value?

53. In regards to the art rejections in view of Wernicke, Applicant argued that the prior art fails to disclose sensing vagus nerve activity or to use a combination of excitatory and non-excitatory signals. However, sensing and applying pacing pulses are claimed in the alternative, and the rejection relies upon the prior art's application of pacing pulses. Applicant discloses that pacing pulses are signals having 1-20mA amplitude and non-excitatory pulses are those having an amplitude of 1-7mA (see col. 17, lines 6-7 of US 7,006,871). Wernicke discloses applying a signal having these

parameters in Table II. The examiner maintains that, because Wernicke discloses an apparatus that generates a signal having the same parameters, the apparatus is capable of producing the effects that Applicant claims. In regards to placement location of the electrode, Applicant argued that Wernicke's electrode is neither disclosed as attached to muscle, nor capable of being attached to muscle because nerve electrodes generally encircle the nerve. However, the examiner maintains the position that Wernicke's disclosure of attachment "at or near the stomach" is disclosure of attachment to the stomach; and any conductive electrode including the nerve electrodes disclosed by Wernicke can be attached to the stomach by, *e.g.*, a suture (see Fig. 3 of Wernicke). As an apparatus claim, Wernicke's electrode only need be capable of such attachment.

Conclusion

54. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762